IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JODI GILL, as Representative and Next Friend of GLENN OSCAR GILL, a Long Term Care Facility Resident, on his behalf and on behalf of all others Similarly Situated and GREG HUBERT, as Representative and Next Friend of NETHIA KNIGHT, a Long Term Care Facility Resident, on her behalf and on behalf of all others Similarly Situated Plaintiffs, vs. PENNSYLVANIA DEPARTMENT OF HEALTH Health & Welfare Building 8th Floor West 625 Forster Street Harrisburg PA 17120 and RACHEL LEVINE, M.D. In Her Official Capacity as Secretary of Health of the Commonwealth of Pennsylvania Defendants	Hon. Chad Kenney Case No. 20-cv-02038 COMPLAINT - CLASS ACTION

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SECOND AMENDED COMPLAINT – CLASS ACTION

INTRODUCTION

1. This case concerns the Pennsylvania Department of Health (PA DOH) policy and practice of denying appropriate safeguards and care to nursing home residents (Long Term Care Facility residents) in the Commonwealth of Pennsylvania, in violation of the Rehabilitation Act, 29 U.S.C. § 794, the Americans with Disabilities Act, 42 U.S.C. §§ 12131-12134, 42 U.S.C. §§ 12181, et seq.; the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i); and federal and state regulations concerning inspections and investigations of Long-Term Care Facilities (LTCFs), including the Social Security Act, 42 U.S.C. § 301, et seq., and its implementing regulations, 42 C.F.R. 483.1 et seq.; the Civil Rights Act, 42 U.S.C. § 1983 as it applies to the Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1396r et seq.; and the Pennsylvania Disease Prevention and Control Law, 35 P.S. §521.1 et seq.

2. This case also concerns violations of the substantive due process protections of the 14th Amendment to the U.S. Constitution. Specifically, the LTCF residents have been deprived of their liberty and dignity rights as a direct result of the failure of the policies of the Pennsylvania Department of Health.

3. This case also concerns biomedical research without authorization or consent. These claims are based on the Nuremburg Code and Declaration of Helsinki. These lay out the minimum conduct required governing biomedical research on human beings, and also raise 14th Amendment claims with regard to substantive due process.

FACTS APPLICABLE TO ALL COUNTS

4. All prior paragraphs are hereby incorporated by reference as thought each were fully set forth at length herein.

5. The PA DOH is tasked with ensuring the safety and health of all Pennsylvania citizens including the residents of Long-Term Care Facilities (LTCFs) and enforcing proper facility operation and conduct. Moreover, specifically with regard to COVID-19, the Governor has charged the Department of Health with the responsibility "to conduct public health and medical coordination for COVID-19 throughout the Commonwealth." See Exhibit A.

6. The PA DOH receives federal funds from many sources, including funding from the Federal Emergency Management Agency (FEMA) for the specific purpose of fighting SARS-CoV2.

7. The PA DOH is required to inspect LTCFs to ensure the safety and health of the residents pursuant to the Code of Federal Regulations under the Social Security Act.

8. Residents of LTCFs are disabled as defined by the Rehabilitation Act.

9. These inspections have come nearly to a halt, thereby putting all LTCF residents at risk of infectious disease transmission. Specifically, these residents are at high risk for contracting SARS-COV-2 (the virus that causes COVID-19) which is becoming pervasive within the community-at-large, and which is easily transmissible from close contact (respiratory droplets) and from surfaces (fomites).

10. The failure of the PA DOH to conduct inspections has also resulted in the apparent biomedical experimentation on residents under the guise of clinical trials. It is unlikely that such egregious conduct could have occurred had inspections not been halted.

11. Residents of LTCFs are the most medically fragile and high-risk members of our society. The decision to stop inspections of LTCFs was made arbitrarily and without consideration for the health, safety, and welfare of the residents.

12. By severely limiting the number of facility inspections the PA DOH has caused a direct, present, and credible threat to the health and wellbeing of the LTCF residents; and has caused death and injury.

13. The current public health emergency[1] presents discrete and specific dangers to high risk groups. The disabled are at high risk individually. Disabled individuals residing in LTCFs are at higher risk because of their disabilities and their close proximity to others.

14. The Pennsylvania Disease Prevention and Control Law gives the PA DOH through the Secretary of Health, and local boards of health, responsibility to safeguard the health and wellbeing of the citizens of the Commonwealth of Pennsylvania and requires the PA DOH to take action to

[1] Governor Wolf issued an Emergency Order effective March 16, 2020 (Ex A) which requires Pennsylvania residents to stay at home unless they are essential workers. A subsequent guidance from the U.S. Health and Human Services Department (Ex B) on March 13, 202 directed facilities to self-evaluate for infection control purposes. A second guidance issued on March 23, 2020 directed state departments of health to prioritize only certain types of inspections. (Ex C).

mitigate the spread of disease. This action cannot be taken in a manner which harms certain sectors of the state's citizens. When the Secretary fails to act, anyone may move to enforce the law. 35 P.S. § 521 et seq.

15. Residents of LTCFs cannot adequately distance themselves from others, thereby placing them at high risk for community infection. Moreover, staff are not properly equipped with Personal Protective Equipment (PPE) sufficient to prevent infection and cross contamination; and testing is not taking place to identify residents and staff who may be ill and able to transmit SARS-COV-2. This is in contrast to the type of infection control and testing available to those who reside outside of LTCFs. This is especially significant because residents of LTCFs cannot simply leave to obtain a test. They are at the mercy of the facilities in which they reside which are, in turn, at the mercy of the DOH and its policies.

16. The control of infection spread outside LTCFs is also wielded by the PA DOH and all management direction comes from the Pennsylvania Secretary of Health, Dr. Rachel Levine and her staff. The application of this authority is disparate and places the LTCF disabled in a higher risk category solely because of their disability.

17. The Pennsylvania Department of Health has a history of segregating the disabled from the non-disabled when considering who is to be protected and receive appropriate care and treatment during the current public health emergency. PA DOH issued Interim Guidelines on March 22, 2020 which applied as follows:

> "When a situation is statewide: These triage guidelines apply to all healthcare professionals, clinics, and facilities in the Commonwealth of Pennsylvania. The guidelines apply to all patients."[2]

Only after a complaint was lodged with the Office of Civil Rights of the Department of Health and Human Services, were these guidelines revised. The intent of the Guidelines was to keep the disabled from using resources which could be allocated to the non-disabled, thereby causing them harm. This was a blatant attempt to create policy which stated that the lives of the

[2] A copy of the Interim Guidelines can be found here: https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/COVID-19%20Interim%20Crisis%20Standards%20of%20Care.pdf (Version 2, accessed 4/27/20); https://int.nyt.com/data/documenthelper/6850-pennsylvania-triage-guidelines/02cb4c58460e57ea9f05/optimized/full.pdf (Version 1, accessed 4/27/20)

disabled are not as valuable as the lives of those who are not disabled. This is the essence of discrimination solely on the basis of disability.

18. Moreover, the PA DOH had knowledge that at least one LTCF was experimenting on its residents with unproven, unauthorized medication in an attempt to see if it prevented them from contracting COVID-19. The PA DOH failed to take action.

19. PA DOH had knowledge of poor conditions at many LTCFs and failed to take any substantive action that would have addressed or improved these conditions, including the failure to physically inspect and assist these facilities with infection control, staffing, testing, contact tracing, isolation, and modifications to prevent further spread of disease.

20. Moreover, the PA DOH had a plan in mid-March 2020 to protect LTCF patients using quick response teams of medical professionals who were to have responded to nursing homes as soon as just a few positive cases were confirmed. They were to have shown up within hours of a call for help. But the entire plan and process was shelved without explanation. Now, the PA DOH is apparently only assisting LTCFs "virtually". See, Exhibit "G", Pattani, A., Moss R. "Pa had an early plan to protect nursing home residents from coronavirus, but never fully implemented it." Philadelphia Inquirer. May 9, 2020 (accessed 0745 a.m.).

21. The Quick Response Team Process was to have operated through the state's Regional Healthcare Coalitions. The Response Teams would be activated from the Healthcare Branch of the DOH, and arrive at the facility in need within six hours, and immediately conduct an assessment on-site. They would provide any necessary training to staff and assist with contact tracing. A copy of version four of the Quick Response Team Process document is attached hereto as Exhibit I.

22. The PA DOH never implemented the Quick Response Team Process Plan. No reason for this decision has been publicly provided.

23. By mid-March 2020, the DOH was aware that COVID-19 was going to have a devastating effect on LTCF residents. This is evidenced by their preparation of a Quick Response Plan to address infections in these facilities in the earliest stages, and their stated intent to conduct contact tracing and provide other assistance for the protection of the residents.

24. Most residents in the Commonwealth's LTCFs have not been tested for COVID-19. Some facilities that have positive cases are treating all of the residents as if they were positive. Many

facilities do not have the capacity to cohort or segregate their residents thereby separating the positive from the negative patients.

25. The DOH had no published guidance for LTCFs with regard to testing, tracing and isolation until May 12, 2020. The Guidance issued on March 18, 2020 did not address testing, provided no information on how testing could be obtained, has no information with regard to mitigation of disease among residents or staff, except to state that no visitors should be permitted. See, collectively, Exhibit J. These exhibits, especially the Health Alert Notice ("HAN") from May 12, 2020, show that the DOH was not supplying tests, was not helping to organize testing, and was not actually mandating testing, but only suggesting it – and only if the facility could find enough tests to do it.

26. While testing centers were set up at varying locations within the state, there was no testing or insufficient testing being conducted within LTCFs or on their staff.

27. The DOH went from apparent concern for the brewing tsunami of infections in LTCFs when it created its March 2020 Quick Response Team Plan to not recommending universal testing until May 12th. Had DOH implemented its Quick Response Team Plan in mid-March, a significant number of deaths could have been prevented.

28. In fact, as late as April 3, 2020 (and without modification until the HAN issued May 12, 2020) DOH specifically instructed LTCFs not to test asymptomatic staff or residents without specific authorization from DOH. (See Exhibit "K"). At the time, DOH knew or should have known that the asymptomatic spread was a real danger, especially in enclosed settings. See Exhibit "O".

4. SARS-CoV-2 Testing

Do not perform routine laboratory testing of asymptomatic staff or residents for COVID-19 (unless instructed by DOH to do so). Follow guidance in March 9 HAN regarding work exclusions after health care-associated exposures; facilities will need to make their own decisions regarding exclusion of asymptomatic HCWs based on their local epidemiology and staffing needs consistent with your crisis standards of care and emergency preparedness planning.

29. The application of DOH policies, and the lack of policies in some areas, created a hybrid category of citizens who were essentially detained against their will and their health and well-being left to the luck of the draw relative to each facility's ability to acquire its own PPE, test kits, and expertise.

30. There exists a continuing failure to establish, implement, and/or enforce appropriate training, testing, tracing, isolating or any other aspect of virus mitigation on the part of the DOH and the Secretary. This rises to the level of deliberate indifference, especially given the Quick Response Plan that was never implemented. This shows a depth of knowledge of the problem and how bad it could get without intervention. Yet, there was no intervention. There was a continuing adherence to an approach that they knew or should have known would fail to prevent infection and injury among the residents.

31. The action that the DOH failed to take (the Quick Response Team Plan) and the inaction that replaced that plan are, for purposes of the Plaintiffs' claims, a result of a "policy" which was not articulated but federal law and the residents' liberty and due process rights were violated nonetheless.

32. As a result, under color of state law, the defendants deprived the LTCF residents of their liberty and due process rights.

33. LTCFs in Pennsylvania have been asking for help from the PA DOH for many weeks yet have received very little in response to their pleas. See, collectively, articles attached as Exhibit "H".

34. The Commonwealth of Pennsylvania and its Department of Health have a non-delegable duty to protect the wellbeing, health, and safety of its citizens and has a *parens patriae* duty to undertake and sustain this protection.

35. The DOH's policies with regard to the treatment, oversight, testing, isolation and care of LTCF residents, left out the residents of LTCFs which was discriminatory. DOH's policies denied Plaintiffs the opportunity to participate in and benefit from publicly funded public health initiatives, the same initiatives that are available to the general public (e.g. ability to be tested the ability to be segregated from those who are infectious, the ability to leave to protect themselves). LTCF residents are isolated, unable to leave to avoid infection. Without universal testing, their isolation with potential carriers of disease is not only a violation of their rights, but a public health failure.

36. The key to mitigating this kind of novel virus is testing, tracing, and rapid response. In a congregate setting, the failure to do these significantly increases the risk of disease spread.

37. The Commonwealth has the funds for this testing to be done and can provide those funds to DOH if needed. See Exhibit "M". Despite the availability of the money for this necessary testing

(which will result in action that serves to protect the facility residents), the state will not coordinate, fund, or take responsibility for this critical aspect of care. See Exhibit "N".

38. To be clear, the R_0 of SARS-CoV2 is between 2 and 3. This means that every infected person will infect two to three others, and so on. This is exponential spread. Without testing everyone, the asymptomatic spreaders will not be identified, and the loop will never be closed.

39. If immediate steps are taken to test, trace, and isolate, the R_0 can be brought under 1 which will slow the virus down while a vaccine is tested and a vaccination program can commence. The time to prevent the now more than 5,000 deaths has passed. But, the remaining population of these facilities still has a chance to be spared if steps are taken now. Time is of the essence.

40. Because of the number of infections and deaths currently in LTCFs in Pennsylvania[3], the situation is emergent and there is imminent risk of injury and death to every facility resident which remains ongoing. Therefore, Plaintiffs, on behalf of persons residing within LTCFs in the Commonwealth of Pennsylvania, seek a preliminary injunction requiring Defendants to immediately take steps to:

    a. Coordinate and oversee the testing, contact tracing, isolation, resident monitoring, cohorting and/or quarantine of a residents and staff;

    b. Contract directly with labs for testing with results reported directly to each facility and the PA DOH;

    c. Continue to provide testing, contact tracing, isolation, etc. of all staff on a weekly basis; and on all new transfers or admits before admission to the facility;

    d. Provide residents with appropriate PPE which may be as simple as cloth masks;

    e. Appoint and direct appropriate and qualified personnel to assist facilities in person with the care of residents, including train-the-trainer programs;

    f. Maintain records subject to inspection by appropriate authorities, including the Court or appointed Master;

[3] As of midnight on May 30, 2020, the following data is reported by the PA DOH: 71,926 cases statewide with 5,555 deaths; 15,486 cases in LTCF residents with 3,540 deaths of LTCF residents. This constitutes nearly 64% of the total deaths in the state on this date. See Exhibit "L".

41. Plaintiffs therefore bring this action on behalf of all class members to ensure that they are not subject to ongoing and incipient harm as a result of the failure of the PA DOH to enforce regulations for the health, safety and wellbeing of the class members.

42. Plaintiffs further seek additional relief, outside the confines of a preliminary injunction, as follows:

    a. Accommodate all class members by uniformly enforcing infection control and other regulations in each and every LTCF in the Commonwealth, to include ongoing testing of new residents and staff on a regular basis;

    b. Implement a long-term plan for the control, mitigation, and treatment of COVID-19 within LTCFs;

    c. Amend the requirements of LTCF emergency preparedness plans to include protocols for novel viruses as identified by CDC, and/or the World Health Organization;

    d. Provide ongoing training for all LTCF staff (which can be accomplished via a train-the-trainer program);

    e. Create a long-term framework for the continued monitoring of residents and staff in LTCFs for COVID-19, which includes reporting of surveillance, cases, and exposures directly through the DOH web portal by each facility on a regular basis.

43. In support of Plaintiffs' claims, Plaintiffs have obtained expert guidance and opinion.
    a. The Declaration of Kenneth Williams, M.D. is attached hereto as Exhibit "P". Dr. Williams is an emergency physician, and director of emergency medical services, program director of the EMS fellowship and professor of medicine at the Warren Alpert School of Medicine at Brown University. His CV is attached to his Declaration.
    b. The Declaration of Larry Brilliant, M.D. is attached hereto as Exhibit "Q". Dr. Brilliant is a physician and consultant in public health, epidemiology and pandemic. He was on the World Health Organization team that eradicated smallpox and he worked on the polio eradication program in India. His vast experience now assists organizations to mount effective responses to the COVID-19 pandemic. His CV is attached to his Declaration.
    c. The Declaration of D. Holmes Morton, M.D. is attached hereto as Exhibit "R". Dr. Morton is a physician and consultant in pediatrics, genetics, epidemiology and

community/public health. His experience tracing the causes of disease in insular communities is well known. His CV is attached to his Declaration.

d. The Declaration of Edwin Naylor, Ph.D. is attached hereto as Exhibit "S". Dr. Naylor is a scientist, teacher, and consultant in genetics, epidemiology and public health. He is a laboratory director and has the capacity to test every LTCF resident in Pennsylvania.

PARTIES

44. Plaintiff is Jodi Gill. She is authorized to take this action on behalf of her father, Glenn Oscar Gill, age 81, who is a resident of Brighton Rehabilitation and Wellness Center in Beaver, Pennsylvania. Mr. Gill suffers from disabilities within the meaning of the Rehabilitation Act, including advanced dementia and cardiovascular disease. Mr. Gill has been a resident at Brighton since September 25, 2019. She is a class representative.

45. In early April, Brighton announced that it would treat all of its residents as presumptively positive. On April 10th, Ms. Gill was called by a nurse at the facility and convinced to sign a "consent" for an experimental drug study she was told was to find out whether the drug combination of hydroxychloroquine and zinc would prevent infection with COVID-19. The full document is attached as Exhibit "D" and is as follows:

CONSENT FOR EXPERIMENTAL POST EXPOSURE PROPHYLAXIS DURING A NATIONAL PANDEMIC

I, _____, understand and agree that:

1. The United States is currently under a pandemic, or widespread infection, of the COVID-19 virus, which is a potentially fatal and easily transmittable virus that primarily effects the ability of a person to breathe and can result in serious injury or death.

2. At the time of this Consent, there is no known medicine that can prevent someone from being infected with COVID-19.

3. Medical research is currently underway to determine if a person taking the drug hydroxychloroquine in conjunction with a zinc tablet can be medically prevented from becoming infected with COVID-19.

4. The use of hydroxychloroquine in conjunction with a zinc tablet is not currently approved by the U.S. Food and Drug Administration (FDA) for preventing a person from being infected with COVID-19. Because this treatment is not FDA-approved, taking hydroxychloroquine in conjunction with a zinc tablet is an "off-label" use, which is to say that the drug manufacturers of hydroxychloroquine, nor the FDA, have said the drug can be, or should be, used to prevent a person from becoming infected with COVID-19.

5. Generally, hydroxychloroquine has few side effects when used for short periods. The most common side effect is upset stomach. However, some serious side effects such as injury to the heart may occur. In addition to these risks, the use of hydroxychloroquine and zinc may harm you in unknown ways, and could cause serious injury, sickness, permanent injuries, and/or death.

6. Understanding the risks associated with the off-label and experimental use of hydroxychloroquine and zinc tablets to prevent becoming infected with COVID-19, I wish to proceed with this treatment as I believe it to be the best course of action in the current National Emergency.

Date: _____ Time: _____

Patient Signature: _____

Witness Signature: _____ Printed name: _____

46. There is no evidence that this "study" was approved by an Institutional Review Board, or that a Data Safety Monitoring Board was engaged, or that any kind of actual informed consent was sought or given. In fact, Ms. Gill was coerced to sign the form because she was told that it would help her father and by not signing it, she would not be helping him. She was told that there were hundreds of people who had to be called about the "study" and that she needed to hurry up and make up her mind. Emails between Ms. Gill and the facility as well as the Director of Skilled Nursing Facilities for the Commonwealth of Pennsylvania are attached hereto as Exhibit "E".

47. Mr. Gill has been exposed to SARS-COV-2. Since the filing of the first amended complaint, he has tested positive for COVID-19. It is unknown if he has suffered physical injury as a result of the unapproved biomedical research study that was conducted on him and hundreds of others in the Brighton facility.

48. The other residents at Brighton as well as at other LTCFs are at immediate risk of contracting COVID-19 and are clearly at immediate risk of being experimented upon. These individuals represent the most fragile in our society and deserve protection, not exploitation

49. Plaintiff is Greg Hubert. He is authorized to take this action on behalf of his grandmother, Netha Knight, age 96, who is a resident of York Rehabilitation and Nursing Center in Philadelphia, Pennsylvania. Ms. Knight suffers from disabilities within the meaning of the Rehabilitation Act, including dementia, hypertension, diabetes and ambulation difficulties. Ms. Knight has been a resident at York for four years. She is a class representative.

50. York Rehabilitation and Nursing Center has COVID-19 -positive patients. Upon information and belief, Ms. Knight was recently moved from her room on the second floor which she shared with two other residents, to the first floor (to a room also with two other residents) which is known to be the COVID-19 -positive floor. At the time she was moved, her family believed she was COVID-19 -negative. Ms. Knight was apparently tested for COVID-19 but the results have not been provided.

51. These named plaintiffs are only two of the more than 75,000 nursing home residents in Pennsylvania. The situations and conditions of their loved ones are not unique. See, Exhibit "F", Declaration of George Emerson (complaints to PA DOH concerning conditions and infection at Brighton were met with no response).

52. Defendant is the Pennsylvania Department of Health which is the department responsible for the inspection of LTCFs and enforcement of the infection control and other regulations applicable to them, as well as the enforcement of applicable public health statutes and regulations. PA DOH is responsible for safeguarding the health of the citizens of the Commonwealth, especially during times of public health emergency.

53. Defendant is Rachel Levine, M.D., in her official capacity as Secretary of Health of the Commonwealth of Pennsylvania.

JURISDICTION

54. All previous paragraphs are hereby incorporated by reference as though each were fully set forth herein.

55. This is an action for declaratory and injunctive relief to enforce the Plaintiffs' rights as aforesaid. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 and §§1343(a)(3) and (4) This action arises under Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, et seq.; the Americans with Disabilities Act, 42 U.S.C. §§ 12131-12134, 42 U.S.C. §§ 12181, et seq.; the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i); the Social Security Act, 42 U.S.C. § 301, et seq., and its implementing regulations, 42 C.F.R. § 483.1 et seq.; the Civil Rights Act, 42 U.S.C. § 1983 as it applies to the Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1396r et seq.; and the Pennsylvania Disease Prevention and Control Law, 35 P.S. § 521.1 et seq.

56. This action also arises under the 14th Amendment to the U.S. Constitution relative to claims for violation of substantive due process rights of each class member.

57. This Court has supplemental jurisdiction under 28 U.S.C. 1367 over Plaintiffs' claims under the Pennsylvania state and local laws and regulations prohibiting disability discrimination; the public health laws and regulations, and the laws and regulations regarding LTCF inspection, safety, and control.

58. Venue properly lies in this district pursuant to 28 U.S.C. § 1391(b).

CLASS ACTION ALLEGATIONS

59. All prior paragraphs are hereby incorporated by reference as though each were fully set forth herein.

60. Plaintiffs bring this action pursuant to Rule 23(a) and Rule 23(b)(2) of the Federal Rules of Civil Procedure on their own behalf and on behalf of all others similarly situated.

61. Plaintiffs' class consists of all individuals in Pennsylvania who are residents of Long-Term Care Facilities (LTCFs) all of whom are disabled within the meaning of the Rehabilitation Act, for the reasons as aforesaid.

62. The class is so numerous that joinder of all members is impracticable.[4]

63. Upon information and belief, based on the number of LTCF residents and the number of LTCFs in Pennsylvania, and the highly infectious nature of SARS-COV-2, that every LTCF resident is at incipient risk for infection with SARS-COV-2, and subsequent community transmission to others. These residents are also at immediate risk for exploitation via unauthorized biomedical research.

64. The laws and regulations which address the nature of this action and that form the basis of this complaint are common to all members of the class. The relief sought will apply to all of them.

65. Questions of law common to the members of the class include whether defendants violated the Rehabilitation Act, the Americans with Disabilities Act, the Social Security Act, the Patient Protection and Affordable Care Act, the Pennsylvania statutes and regulations relative to the public health and infection control, and other regulations relative to LTCFs, and common law duties, by failing to conduct activities and inspections as aforesaid, and to ensure that the disabled are afforded the same protections as the rest of the public.

66. The claims of the Plaintiffs are typical of the claims of the entire class. Defendant's violation of the laws as alleged herein has deprived Plaintiffs and members of the class to be deprived of the safety and wellbeing afforded to the rest of the public by the PA DOH. Therefore, all class

[4] There are nearly 76,000 nursing home residents in Pennsylvania according to the 2018-2019 data from the State which is the most recent census available. (https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx Accessed 5/3/2020).

members will suffer the same or similar injuries for the purposes of the injunctive and declaratory relief sought.

67. The named plaintiffs are capable of fairly and adequately representing the class and protecting interests. Counsel for the Plaintiffs are attorneys with substantial class action litigation experience as well as substantial experience in litigating on behalf of plaintiffs with disabilities. Counsel are aware of no conflicts among members of the proposed plaintiff class.

68. The prosecution of separate actions by individual members of the class would create a risk of inconsistent and varying adjudications that would establish incompatible standards of conduct for the defendant.

69. The prosecution of separate actions by individual members of the class would also create a risk of adjudications with respect to individual members which would, as a practical matter, substantially impair the ability of other members to protect their interests.

70. Defendants have acted or refused to act on grounds generally applicable to the class, making appropriate injunctive and declaratory relief with respect to the class as a whole.

STATUTORY FRAMEWORK

71. All prior paragraphs are hereby incorporated by reference as though each were fully set forth herein.

72. Section 504 of the Rehabilitation Act, 29 U.S.C. § 794 prohibits federally funded programs or activities from excluding, denying benefits to, or discriminating against, an "otherwise qualified individual with a disability in the United States. . . solely by reason of her or his disability."

73. Title II of the ADA prohibits public entities (such as state and local governments) from excluding people with disabilities from their programs, services, or activities, denying them the benefits of those services, programs, or activities, or otherwise subjecting them to discrimination. 42 U.S.C. §§ 12131-12134.

74. Title III of the ADA imposes almost identical prohibitions on public accommodations, which includes hospitals and other health care providers. 42 U.S.C. §§ 12181(7)(F), 12182. Specifically, Title III bars health care providers from excluding people with disabilities from the full and equal enjoyment of their services and facilities. 42 U.S.C. §

12182(a). Congress construed this non-discrimination mandate broadly to bar, *inter alia*: use of eligibility criteria that screen out or tend to screen out people with disabilities; failure to make reasonable modifications to policies, practices, and procedures necessary to avoid discrimination; and aiding or perpetuating discrimination by others. 42 U.S.C. §§ 12182(b)(1)(D)(ii), 12182(b)(2)(i)-(ii); *accord* 28 C.F.R. §§ 36.204, 36.301, 36.302.

75. The breadth of Section 504's prohibition on disability discrimination is co-extensive with that of the ADA.

76. Section 1557 of the ACA provides that no health program or activity that receives federal funds may exclude from participation, deny the benefits of their programs, services or activities, or otherwise discriminate against a person protected by Section 504 of the Rehabilitation Act, 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i). This includes an obligation to make reasonable modifications in policies, practices, and procedures necessary to avoid discrimination. 45 C.F.R. § 92.205

77. The Social Security Act, 42 U.S.C. 301 et seq is enforced relative to LTCFs via the Code of Federal Regulations, specifically 42 C.F.R. 483.1 et seq, which govern oversight and requirements for the operation of LTCFs and the enforcement of those operations and the safety, health, and welfare of LTCF residents. DOH is obligated to follow the rules from CMS concerning inspection and infection control in LTCFs as part of its mandate.

78. The Pennsylvania Department of Health accepts money from the federal department of Health and Human Services as well as the Federal Emergency Management Agency (FEMA) specifically with regard to the emergency caused by SARS-CoV2. As such, the DOH and Secretary Levine are obligated to follow and abide by the Rehabilitation Act, the ADA, ACA, Social Security Act, Federal Nursing Home Reform Amendments, Civil Rights Act, and all of their implementing regulations.

79. The Pennsylvania Department of Health has established rules, guidelines and Health Alert Notices (collectively referred to as policies) which dictate the treatment and protection of LTCF residents. The residents of LTCFs are subject to the Governor's emergency declaration and therefore to the rules set by the DOH and Secretary Levine, which dictate their daily lives.

80. The Rehabilitation Act's implementing regulations further provide that "[a] [federal funds] recipient shall make reasonable accommodation to the known physical or mental limitations of an

otherwise qualified handicapped applicant. . . unless the recipient can demonstrate that the accommodation would impose and undue hardship on the operation of its program." 28 C.F.R. 41.53.

81. An entity's failure to provide a reasonable accommodation to a disabled individual that the individual needs in order to enjoy meaningful access to the entity's benefits and/or services constitutes discrimination under the Rehabilitation Act.

82. A disability includes "a physical or mental impairment that substantially limits one or more major life activities of [an] individual[.]" See 29 U.S.C. § 705(20(B) (citing 42 U.S.C. § 12102(1)).

83. A major life activity includes, but is not limited to the ability to ambulate, eat independently, [multiple citations] 29 U.S.C. § 705(20)(B) (citing 42 U.S.C. § 12102(2)).

84. Included in the Rehabilitation Act's definition of "program or activity" are "all of the operation of . . . an entire corporation. . . or other private organization . . . which is principally engaged in the business of providing. . . health care. . . " 29 U.S.C. § 794(b)(3)(A)(ii). Any entity receiving federal financial assistance is subject to the Act. 29 U.S.C. § 794(a). All of the operations of the department, agency…or other instrumentality, any part of which is extended federal financial assistance" is subject to the Act. 29 U.S.C. § 794(b)(1)(A) and (B).

85. The Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1395i-3 et seq., and §1396r et seq. create rights which inure to the individual nursing home resident. The Plaintiff seeks redress of the violations of these rights through 42 U.S.C. § 1983. These rights include:

    a. A safe and infection-controlled environment;

    b. Prevention of the development of disease;

    c. The right to have a safe environment free from discrimination;

    d. The right to have all violations of the residents' rights investigated by the State which is obligated to provide oversight and assurance that the needs and rights of the residents are being met and respected; and to require the conditions are such that the residents' health and welfare are protected;

    e. The right to have immediate steps taken by the State for deficiencies and risks to the residents' health and safety.

86. The Pennsylvania Disease Prevention and Control Law("DPCL") gives the PA DOH through the Secretary of Health, and local boards of health, responsibility to safeguard the health and wellbeing of the citizens of the Commonwealth of Pennsylvania and requires the PA DOH to take action to mitigate the spread of disease. When the Secretary fails to act, anyone may move to enforce the law. 35 P.S. § 521 et seq. The main purpose of the DPCL is to institute a system of mandatory reporting, examination, diagnosis, and treatment of communicable diseases. A public health system depends on public oversight and accountability.

87. Federal regulations require that a skilled nursing facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infection. 42 C.F.R. § 483.80. The regulations also require that the facility's infection control program must include minimum elements which include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, and that they must follow national standards. 42 C.F.R. §§ 483.80(a) and (a)(1).

88. A skilled nursing facility is required to operate and provide services in compliance with all applicable federal, state, and local laws and regulations, and within accepted professional standards and principles which apply to professionals providing services in such a facility. 42 U.S.C. § 1395i-3, et seq.

89. Moreover, a state must maintain procedures and adequate staff to investigate complaints of violations and to monitor on-site on a regular basis a facility's compliance with the requirements of applicable federal rules and regulations. 42 U.S.C. 1395i-3, et eq.

90. Defendant is principally engaged in the provision and oversight of health care services; policy enactment, enforcement, oversight and coordination.

FRAMEWORK OF THE NUREMBURG CODE & DECLARATION OF HELSINKI

91. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

92. The Nuremberg Code and the Declaration of Helsinki are the minimum international standards of conduct governing biomedical research on human subjects; they are in essence world statutes to which the citizens of all nations are subject.

93. The Nuremberg Code, drafted in response to the horrors of Nazi experimentation on human subjects, set forth basic principles "to satisfy moral ethical and legal concepts."

94. The Nuremberg Code provides in pertinent part:

> The voluntary consent of the human subject is absolutely essential. . . . . before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
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> . . .
>
> The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem understudy that the anticipated results will justify the performance of the experiment.
>
> . . .
>
> The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
>
> . . .
>
> Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
>
> . . .
>
> The experiment should be conducted only by scientifically qualified persons.

95. The World Health Organization established the Declaration of Helsinki to further the goals of the Nuremberg Code and to set the minimum acceptable standards in all nations in which human clinical trials are conducted.

These include:

> Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
>
> . . .
>
> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
>
> . . .
>
> Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person..
>
> . . .
>
> Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject.

> Concern for the interests of the subject must always prevail over the interest of science and society.
>
> . . .
>
> The right of the research subject to safeguard his or her integrity must always be respected.
>
> . . .
>
> Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable.
>
> . . .
>
> In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

96. The common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial, and such is a right of all citizens under the Constitution of the United States and of the Commonwealth of Pennsylvania.

97. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiffs and the class to be treated with dignity.

98. Defendants' actions, as set forth above, violate the substantive due process rights under the 14th Amendment to the U.S. Constitution.

DEFENDANTS' FAILURE TO COMPLY WITH THE ADA, REHABILITATION ACT, SOCIAL SECURITY ACT, ACA FNHRA, the CIVIL RIGHTS ACT (Sec. 1983) and the DISEASE PREVENTION AND CONTROL LAW

99. All prior paragraphs are hereby incorporated by reference as though each were fully set forth herein.

100. The Pennsylvania Department of Health has a history of segregating the disabled from the non-disabled when considering who is to receive appropriate care and treatment during the current public health emergency. PA DOH issued Interim Guidelines on March 22, 2020 which applied as follows:

> "When a situation is statewide: These triage guidelines apply to all healthcare professionals , clinics, and facilities in the Commonwealth of Pennsylvania . The guidelines apply to all patients."[5]

[5] See, URLs at footote 2.

Only after a complaint was lodged with the Office of Civil Rights of the Department of Health and Human Services, were these guidelines revised, yet they still contain language tacitly directing the rationing of care at the expense of the disabled. The intent of the Guidelines was to keep the disabled from using resources which could be allocated to the non-disabled, thereby causing them harm. This is the essence of discrimination solely on the basis of disability.

101. As aforesaid, Defendants have already excluded, denied services to, and discriminated against, the disabled residents of LTCFs in Pennsylvania in violation of the Rehabilitation Act. As a result, these individuals have been injured, died or are in danger of incipient injury and death, as aforesaid.

102. Defendants knew or had reason to know of the disabilities of these individuals at the time the decision was made to fail to take warranted, required and appropriate action that would have safeguarded these individuals.

103. Defendants knew or should have known that their failure to implement the proper plans to care for LTCF residents and protect them from the spread of SARS-CoV2 would have a terrible and devastating effect on these residents. At the time of the decision was made to shelve the Quick Response Team Plan, the entire world was aware that people in close proximity to one another would become ill once infection took hold. The lack of planning and implementation of plans from that point forward constitutes deliberate indifference to the health and well-being of LTCF residents. It has objectively caused them harm as attested by the infection and death rates within LTCFs.

104. Defendant's failure to conduct appropriate inspections, oversight and management of its duties with regard to LTCFs threatens Plaintiff's class members with real, immediate, and substantial harm by impeding their ability to access the safeguards of the laws and regulations designed to protect them.

COUNT ONE

Violation of 29 U.S.C. § 794 – Rehabilitation Act

105. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

106. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs as aforesaid, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.

107. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT TWO

Violation of the Americans with Disabilities Act

108. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

109. As a result of Defendants' policy and practice of segregating Plaintiffs and their class members, as aforesaid, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.

110. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT THREE

Violation of the Affordable Care Act

111. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

112. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their

disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.

113. Moreover under the ACA, discrimination based on age is prohibited. The DOH policies showed a deliberate indifference to the fragility of the individuals in LTCFs as a result of not only disability but also age, for all of the reasons as aforesaid.

114. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT FOUR

Violation of the Social Security Act

115. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

116. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendants are obligated to conduct appropriate inspections and enforcement under the SSA which responsibility they have abrogated to the detriment of the Plaintiffs and class members.

117. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT FIVE

Violation of the Federal Nursing Home Reform Amendments (1983 Action)

118. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

119. As a result of Defendants' policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendants have failed to care for its most fragile citizens. Defendant has excluded them from appropriate

oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendants are obligated to conduct appropriate inspections and ensure proper and appropriate safeguards are in place, and that enforcement under the FNHRA which responsibility they have abrogated to the detriment of the Plaintiffs and class members.

120. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT SIX

Violation of the Pennsylvania Disease Prevention and Control Law

121. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

122. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendant is required under the DPCL to take all action required to prevent, identify, examine, diagnose ad cause to be treated every potential communicable disease within the Commonwealth. These policies must apply equally to all or a violation of the substantive due process right afforded by the 14th Amendment to the U.S. Constitution will result, as it has here.

123. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT SEVEN

Violation of the 14th Amendment to the U.S. Constitution

124. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

125. As aforesaid, Defendants' policies and the application of directives constitute a deliberate indifference to the rights of the LTCF residents. These individuals are unable to leave and were

never given the proper protection afforded to other Pennsylvanians by the DOH and the Secretary.

126. As a direct and proximate result of the Defendants' actions and inactions as aforesaid, Plaintiffs and their class members have been harmed and will continue to be harmed unless steps are undertaken immediately to help them.

COUNT EIGHT

Violations of the Nuremburg Code and Declaration of Helsinki Construed as violations of the right to Substantive Due Process under the 14th Amendment to the U.S. Constitution

127. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

128. The common law has recognized the standards of the Nuremburg Code and the Declaration of Helsinki as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial. These are constitutional rights of dignity under the federal and state constitutions.

129. Violations of these standards results in a substantive due process violation as aforesaid.

130. The Plaintiff and the class members were not afforded these basic rights and suffered as a result.

131. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

DECLARATORY AND INJUNCTIVE RELIEF

132. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.

133. Plaintiff respectfully requests that this Court:

a. Assert jurisdiction over this matter;

b. Issue a preliminary injunction and declaratory judgment in favor of Plaintiffs requiring that Defendants do the following:

i. Coordinate and oversee the testing, contact tracing, isolation, resident monitoring, cohorting and/or quarantine of a residents and staff;

ii. Contract directly with labs for testing with results reported directly to each facility and the PA DOH;

iii. Continue to provide testing, contact tracing, isolation, etc. of all staff on a weekly basis; and on all new transfers or admits before admission to the facility;

iv. Provide residents with appropriate PPE which may be as simple as cloth masks;

v. Appoint and direct appropriate and qualified personnel to assist facilities in person with the care of residents, including train-the-trainer programs;

c. Maintain records subject to inspection by appropriate authorities, including the Court or appointed Master;

134. As part of the larger scope of this action, the Plaintiffs respectfully request that this Court issue an order, directing that the Defendants do the following:

a. Accommodate all class members by uniformly enforcing infection control and other regulations in each and every LTCF in the Commonwealth, to include ongoing testing of new residents and staff on a regular basis;

b. Implement a long-term plan for the control, mitigation, and treatment of COVID-19 within LTCFs;

c. Amend the requirements of LTCF emergency preparedness plans to include protocols for novel viruses as identified by CDC, and/or the World Health Organization;

d. Provide ongoing training for all LTCF staff (which can be accomplished via a train-the-trainer program);

e. Create a long-term framework for the continued monitoring of residents and staff in LTCFs for COVID-19, which includes reporting of surveillance, cases, and exposures directly through the DOH web portal by each facility on a regular basis.

f. Create, adopt, and implement plans to prevent medical experimentation on LTCF residents.

g. Issue a permanent injunction which requires Defendant to follow the guidance of and report to a medical/public health monitor to ensure compliance with standards of care and oversight

h. Award Plaintiffs the costs of this action including attorneys' fees pursuant to statute;

i. Award such other relief as this Court deems just and appropriate

Respectfully submitted,

SHRAGER & SACHS

BY: /s/ Theresa M. Blanco
Robert L. Sachs, Jr., Esquire
Theresa M. Blanco, Esquire
Co-counsel for Plaintiffs

June 1, 2020